

APPENDIX II

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Ezri Peleg et al.
Application No.: 10/587,789
Attorney Docket No.: 27275.005
Filing Date: March 03, 2008
Title: HIGH LYCOPENE TOMATO
VARIETIES AND USE THEREOF

Examiner: Phuong T. Bui
Group Art Unit: 1638

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

Dear Examiner,

In order to assist in the prosecution of this application and the traversal of the claims rejection subjected by the Examiner, I, Ezri Peleg, do hereby declare as follows.

BACKGROUND

My name is Ezri Peleg. I am a plant breeder in the Research & Development Division of Hazera Genetics Ltd. Mivhor, M.P Lachish Darom 79354 Israel. I received my M.sc. degree at the Hebrew University in Rehovot, Israel, on 1996.

My research interests and field of expertise are tomato breeding and phytopatology and crop protection.

PROFESSIONAL OPINION

It is in my capacity as a plant breeder and a researcher in these fields that I offer the following comments and experimental data in the light of my reading of US patent application 10/587,789, (hereinafter referred to as the **present application**), the Office Action of March 07, 2011, the Response to the Office Action, including the set of amended claims attached to this letter and the publication of Levin et al WO 03/057917 A2 cited by the Examiner.

The present application claims robust, hardy, vigorous tomato varieties adapted for growth on a commercial scale, homozygous for the *dg* mutation, producing fruit crop yield comprising an average lycopene content of at least 200 ppm, wherein the plants are devoid of the *dg* linked deleterious traits (amended claim 1). Tomato plants carrying the *dg* mutation are characterized by their dark-green fruits, which, upon ripening, become dark red, due to high lycopene content. However, **the *dg* mutation is known to be linked with deleterious pleiotropic traits** which prevented the use of the high pigment *dg* gene in breeding programs (Sacks E.K. and Francis, D.M. 2001. J. Amer. Hort. Sci. 126(2):221-226). It is emphasised that the term "deleterious traits" cited in claim 1, covered by the traits listed in claim 5 of the present application, namely poor germination rate, shallow root system, brittle stems, thin and/or fragile leaves, premature defoliation, low yield, and small fruit are **acceptable terms** which are commonly understood by tomato breeders in the field. Furthermore, these terms are understood by persons in the art without necessarily having them defined quantitatively. In other words, any tomato breeder knows what is meant by these terms *per se* as applied to attempts to breed commercial plant varieties.

The surprising and unexpected achievement of the present invention is that the tomato varieties of the present application, while homozygous for the *dg* mutation, *do not* show any of the pleiotropic and deleterious effects linked to the *dg* mutation. This is extensively claimed, disclosed and demonstrated in the application. In addition to the high lycopene concentration of the fruits, which is at least 200 ppm (amended claim 1 and Example 1), the tomato varieties of the present invention are devoid of the *dg*-linked deleterious traits, as specifically claimed in the originally filed claims 1 and 5.

The term "deleterious traits" cited in claim 1, and the traits defined in the originally filed claim 5 and in the Description section of the application, are commonly used in

the respective art (i.e. Cornelius S. B et al., PANS, 2006, see p.7927-7928; Sacks E.K. and Francis, D.M. 2001. J. Amer. Hort. Sci. 126(2):221-226, see p. 222; Jarret RL et al, J. Amer Soc. Hort. Sci 109: 873-878; Thompson AE 1961 Proc. Amer. Soc. Hort. Sci 78: 464-473) thus allow one skilled in the art to **objectively** determine deleterious traits. *dg* associated deleterious traits such as brittle stems, fragile leaves and small fruit claimed in claim 5, are conventional terms used by ordinary tomato breeders to describe plant quality and presence of undesirable effects. Examples 1 and 2 of the specification clearly show that the novel high lycopene hybrids of the present application are superior over commercially available varieties examined in production of fruits with significantly higher Total Soluble Solids (Brix), lycopene content, plant quality, fruit size, fruit yield, leaf appearance, and have crop yield which is considered as average to high, relative to a commercial variety (Figs 1, 2 and Tables 2 and 3). The present application defines the average crop yield of the claimed tomato hybrid varieties, (exemplified by hybrid HA3518) as at least 9 Kg/m² (Example 1). The average Brix value of the tomato hybrid varieties of the present invention is defined and exemplified as about 4.5 (Example 2). These values are further defined in the new submitted claims 39-41. Such high yield beneficial traits are a consequence of the absence of the pleiotropic deleterious effects commonly described to be linked to the *dg* mutation (Sacks E.K. and Francis, D.M. 2001. J. Amer. Hort. Sci. 126(2):221-226). Fig. 1 of the present application clearly shows the phenotypic difference between a tomato plant homozygous for the *dg* mutation, which retains the deleterious pleiotropic effects associated with the mutation (A) or is devoid of such effects (B). The apparent difference is sharp and therefore is distinguishable by any person skilled in the art, especially a tomato breeder. Thus the deleterious traits listed in claim 5 can be determined by any person skilled in the relevant art.

In other words, the present invention has successfully provided, as claimed in the currently submitted claim 1, robust, hardy, vigorous tomato varieties adapted for growth on a commercial scale, homozygous for the *dg* mutation, wherein tomatoes grown from these varieties have an average lycopene content of at least 200 ppm, while being devoid of deleterious traits associated with the *dg* mutation, when measured at peak lycopene content.

As further evidence for the common usage and meaning of the deleterious traits defined by the terms listed in claim 5, a document describing official guidelines administered by the Ministry of Agriculture of the State of Israel, directed to breeders of tomato crop varieties, is attached (Appendix I). These guidelines provide the breeders with **qualitative parameters, tested in the field**, to evaluate the suitability of tomato varieties for commercial use. The tomato varieties tests encompass **visual evaluation** of parameters such as endogenous fruit color, presence of veins, jelly, hollowness, "shoulders", vegetative growth, fruit leaf cover, disease resistance, fruit shape, general color, hardness/ solidness of the fruit, healthiness of the plant and pulp/flesh color. It should be emphasised that these parameters are **visually evaluated in the field** by tomato breeders and they are **qualitatively scored by a relative scale** (i.e. poor, high, soft, weak, few, many, solid, good, pronounced and medium) as presented in Table 2 of the attached document (Appendix I). The subsequent conclusion of considering all these visual estimations is a general evaluation with respect to the determination if the crop yield of the specific variety is suitable for **commercial use**.

Thus traits as cited in claims 1 and 5 of the present application are acceptable terms in the field of tomato breeding and their common usage and meaning is understood *per se* by any person skilled in the relevant art.

Verification

I further declare that all statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon

Signed:

A handwritten signature in black ink, appearing to be a stylized 'E' or similar character, followed by a small flourish.

Date: May 29, 2011